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10/728,496	12/05/2003	Punam K. Saha	P-2944	9711

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MONTGOMERY, MCCRACKEN, WALKER & RHOADS, LLP
123 SOUTH BROAD STREET
AVENUE OF THE ARTS
PHILADELPHIA, PA 19109

EXAMINER	
KRASNIC, BERNARD	

ART UNIT	PAPER NUMBER
2624	

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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/728,496	SAHA ET AL.	
	Examiner	Art Unit	
	BERNARD KRASNIC	2624	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *10 October 2008*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-28* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-28* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *05 December 2003* is/are: a)☐ accepted or b)☒ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Response to Arguments

1. The amendment filed 10/10/2008 have been entered and made of record.

2. The Applicant has canceled claim(s) 29-30.

3. The application has pending claim(s) 1-28.

4. Although the Declaration of Felix W. Wehrli is made under 37 CFR 1.131, it is an obvious attempt for a Declaration under 37 CFR. 1.132 where the inventors have stated that Dr. Takahashi was a named author only because his data was used to test and confirm the effect of using the presently claimed method and that Dr. Takahashi was not part of Applicants' present invention and offered no contribution to its conception. Therefore the Declaration filed on 10/10/2008 under 37 CFR 1.132 [not 37 CFR 1.131] is sufficient to overcome the rejection of claims 1-30 based upon 35 U.S.C 102(a) and 103(a) rejections because the art reference Takahashi ("Trabecular Bone Thickness from In vivo MRI using Fuzzy Distance Transform" – May 2002) is now no longer considered prior art. See MPEP 716.10

5. The Declaration of Bryon Gromberg filed on 10/10/2008 under 37 CFR 1.131 has been considered but is ineffective to overcome the Gomberg Doctoral Dissertation Thesis ("In vivo magnetic resonance based virtual bone biopsy" - 2002) reference. The

evidence submitted is insufficient because all the named inventors of the subject matter claimed should be signing the declaration. Also, the evidence submitted is insufficient in that it doesn't discuss the establishment of conception, reduction to practice of the invention, constructive reduction to practice, or due diligence. See MPEP 715.04

6. In response to the amendments filed on 10/10/2008:

The "Claim rejections under 35 U.S.C. 112, first and second paragraph" have been entered and therefore the Examiner withdraws the rejections under 35 U.S.C. 112, first and second paragraph.

The "Claim rejections under 35 U.S.C. 101" have been entered and therefore the Examiner withdraws the rejections under 35 U.S.C. 101.

7. As discussed above in regards to the Declaration under 37 CFR 1.132, Applicant's arguments, see "Response to the Rejection under 35 U.S.C. 102(a) ..." in pages 7-9, filed 10/10/2008, with respect to the rejection(s) of claim(s) 1, 17, 25 and 29-30 under 35 U.S.C. 102(a) have been fully considered and are persuasive. Therefore, the rejection has been withdrawn. However, upon further consideration, a new ground(s) of rejection is made in view of newly applied prior art references. Further discussions are addressed below in the art rejections section.

Drawings

8. The drawings are objected to under 37 CFR 1.83(a). The drawings must show every feature of the invention specified in the claims. Therefore, the steps of [e.g.] obtaining an image, finding a plurality of points in the image to generate a fuzzy subset and computing a fuzzy distance transform of the fuzzy subset, and compiling a plot or revised image based upon the computed fuzzy distance transform must be shown or the feature(s) canceled from the claim(s). No new matter should be entered.

Corrected drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. The figure or figure number of an amended drawing should not be labeled as "amended." If a drawing figure is to be canceled, the appropriate figure must be removed from the replacement sheet, and where necessary, the remaining figures must be renumbered and appropriate changes made to the brief description of the several views of the drawings for consistency. Additional replacement sheets may be necessary to show the renumbering of the remaining figures. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either "Replacement Sheet" or "New Sheet" pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Claim Rejections - 35 USC § 101

9. Claim(s) 1-16 and 17-24 is/are rejected under 35 U.S.C. 101 as not falling within one of the four statutory categories of invention. Supreme Court precedent[1] and recent Federal Circuit decisions[2] indicate that a statutory "process" under 35 U.S.C. 101 must (1) be tied to another statutory category (such as a particular apparatus), or (2) transform underlying subject matter (such as an article or material) to a different state or thing. While the instant claim(s) recite a series of steps or acts to be performed, the claim(s) neither transform underlying subject matter nor positively tie to another statutory category that accomplishes the claimed method steps, and therefore do not qualify as a statutory process. For example the method steps of finding a plurality of points in the image to generate a fuzzy subset and computing a fuzzy distance transform of the fuzzy subset are not tied to another statutory category such as a particular apparatus (i.e. a computer processor for processing the specific method steps). Any amendment to the claim(s) should be commensurate with its corresponding disclosure.

Claim Rejections - 35 USC § 112

10. The following is a quotation of the first paragraph of 35 U.S.C. 112:

> The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

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[1] *Diamond v. Diehr*, 450 U.S. 175, 184 (1981); *Parker v. Flook*, 437 U.S. 584, 588 n.9 (1978); *Gottschalk v. Benson*, 409 U.S. 63, 70 (1972); *Cochrane v. Deener*, 94 U.S. 780, 787-88 (1876).
[2] *In re Bilski*, 88 USPQ2d 1385 (Fed. Cir. 2008).

11. Claim 25 [claims 26-28 are dependent upon claim 25] are rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to reasonably convey to one skilled in the relevant art that the inventor(s), at the time the application was filed, had possession of the claimed invention. *Firstly, the Examiners 35 U.S.C. 101 rejection in the Non-Final Office Action dated 6/09/2008 on pages 5-6 did not suggest to the Applicant to include in the claim [to overcome the 35 U.S.C. 101 rejection] a negative limitation where a computer readable medium should be a "non-signal bearing medium", but rather suggested to include claim language that directly indicates that a computer readable medium isn't identified as a signal bearing medium [one example could be computer readable volatile memory where it shows that the medium is an actual computer memory such as RAM or ROM]. Due to this amendment where the Applicant has included the negative limitation of a "non-signal bearing medium", the specification does not support such language and is therefore considered as new matter. If the Applicant attempts in a future reply to amend the medium to [e.g.] a computer readable volatile memory medium, the Applicant is reminded, any amendment to the claim should be commensurate with its corresponding disclosure [also please provide the Examiner with the location in the specification where such claim language is found so no confusion arises in regards to further new matter issues].*

Appropriate correction is required.

Claim Rejections - 35 USC § 102

12. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

13. Claim 1 is rejected under 35 U.S.C. 102(a) as being anticipated by Borgefors ("Fuzzy border distance transforms and their use in 2D skeletonization" – August 2002, provided in previous Office Action).

Re Claim 1: Borgefors discloses a fuzzy distance transform-based computational method / fuzzy border distance transform for analyzing digital images (see Figs. 2 and 3) defining a volumetric region / 2D or higher dimensions such as 3D of an object from an image (see abstract, Section 2 – Fuzzy border distance transforms, Figs. 2 and 3, skeletonization of objects is performed on 2D digital images [also extendible to higher dimensions such as 3D]) comprising: (a) obtaining an image of the targeted object (see abstract, Section 2 – Fuzzy border distance transforms, Figs. 2 and 3 show obtaining the initial targeted object and then initializing the fuzzy border distance transform and then the resulting skeletonized image produced from the computed fuzzy border distance transform); (b) finding a plurality of points in the image to generate a fuzzy subset / fuzzy border and compute a fuzzy distance transform (FDT) / fuzzy border distance transform of the fuzzy subset / fuzzy border (see abstract, Section 2 – Fuzzy border distance transforms, Figs. 2 and 3 show obtaining the initial targeted object and

then initializing the fuzzy border distance transform and then the resulting skeletonized image produced from the computed fuzzy border distance transform); and (c) compiling a plot or revised image / skeletonized image based upon the computed FDT / fuzzy border distance transform (see abstract, Section 2 – Fuzzy border distance transforms, Figs. 2 and 3 show obtaining the initial targeted object and then initializing the fuzzy border distance transform and then the resulting skeletonized image produced from the computed fuzzy border distance transform).

Claim Rejections - 35 USC § 103

14. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

15. Claims 2-5, 7, 10-11, 13, and 16 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borgefors in view of Wang ("Some sequential algorithms for a generalized distance transformation based on minkowski operations" – IEEE – 1992, pages 1114-1121, as applied in previous Office Action). The teachings of Borgefors have been discussed above.

Re Claim 2: However Borgefors doesn't explicitly suggest assigning to a point in the fuzzy subset its respective fuzzy distance from a complement of a support of the fuzzy subset.

Wang discloses assigning to a point in the subset its respective distance from a complement of a support of the subset (see page 1115, paragraph "Rosenfeld [2] has first proposed a DT based on the ..." and "The medial axis transformation (or skeleton) ...") [this is similar to Borgefors wherein the complement is the border and the medial axis transformation is the skeleton].

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Borgefors's method using Wang's teaching by including such an assignment to Borgefors's Fuzzy Border Distance Transform in order to provide the *Distance Transform basics* to the further developed Fuzzy Border Distance Transform.

Re Claim 3: Borgefors further discloses wherein the support comprises a set of all points in the fuzzy subset / fuzzy border with a value greater than or equal to a support value (see abstract, Section 2 – Fuzzy border distance transforms, the border is determined by initialization using two thresholds and wherein values above [greater than or equal] T_b are definitely part of the object).

Re Claim 4: Borgefors further discloses wherein the FDT / fuzzy border distance transform is in digital cubic space / 3D (see abstract, Section 2 – Fuzzy border distance transforms, Figs. 2 and 3, skeletonization of objects is performed on 2D digital images [also extendible to higher dimensions such as 3D]).

Re Claim 5: Wang further discloses the step of sampling FDT [Borgefors fuzzy border distance transform] values along a medial axis of the support of the fuzzy subset [Borgefors fuzzy border] to estimate regional target object thickness distribution (see Wang, page 1115, paragraph "The medial axis transformation (or skeleton ...", the medial axis transformation is used to estimate the regional thickness by basically getting the skeleton [Borgefors also finds this skeleton as shown in Figures 2 and 3 of Borgefors which is very similar to the applicant's discussion of medial axis in regards to the Applicants specification paragraph 0023 and Applicant's figure 3b and 3c]).

Re Claim 7: Borgefors further discloses wherein FDT / fuzzy border distance transform is computed in digital cubic space / 3D of resolution of target object thickness or smaller (see abstract, Section 2 – Fuzzy border distance transforms, Figs. 2 and 3, skeletonization of objects is performed on 2D digital images [also extendible to higher dimensions such as 3D]).

Re Claim 10: Wang further discloses whereby FDT [Borgefors fuzzy border distance transform] values are sampled along a medial axis directly computed from the fuzzy subset [Borgefors fuzzy border] (see Wang, page 1115, paragraph "The medial axis transformation (or skeleton ...", the medial axis transformation is used to estimate the regional thickness by basically getting the skeleton [Borgefors also finds this skeleton as shown in Figures 2 and 3 of Borgefors which is very similar to the applicant's discussion

of medial axis in regards to the applicants specification paragraph 0023 and applicant's figure 3b and 3c]).

As to claims 11 and 13, the discussions are addressed with respect to claims 4 and 7.

Re Claim 16: Borgefors further discloses applying *one or more* additional steps consisting of skeletonizing / skeletonization (see abstract, Section 2 – Fuzzy border distance transforms, Figs. 2 and 3), feature extracting; analyzing morphological or shape-based object, computing regional object depth; calculating average or regional object thickness distribution; and local scaling. Wang further discloses applying one or more additional steps consisting of skeletonizing / skeleton (see Wang, page 1115, paragraph "The medial axis transformation (or skeleton ...", the medial axis or skeleton [Borgefors also finds this skeleton as shown in Figures 2 and 3 of Borgefors which is very similar to the Applicant's discussion of medial axis in regards to the Applicants specification paragraph 0023 and Applicant's figure 3b and 3c]).

16. Claims 6, 8-9, 12, and 14-15 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borgefors, as modified by Wang, and further in view of Saha ("Scale-Based Fuzzy Connected Image Segmentation: Theory, Algorithms, and Validation" –

2000, pages 145-174, provided by Applicants Information Disclosure Statement - IDS). The teachings of Borgefors as modified by Wang have been discussed above.

However Borgefors as modified by Wang fails to explicitly suggest, as recited in claim 6 wherein the target object comprises bone marrow space, cortical bone, blood vessels or lung airways; as recited in claim 8 wherein the target object is in or from an animal or human subject; as recited in claim 9 wherein the image is obtained by magnetic resonance or computed tomography.

Saha discloses fuzzy connectedness algorithm which are effective on MRI's, blood vessel definition in MR angiography and in separation of bone and soft tissues from skin in CT images [as recited in claim 6 wherein the target object comprises bone marrow space, cortical bone, blood vessels / blood vessel definition in MR angiography or lung airways; as recited in claim 8 wherein the target object is in or from an animal or human subject / bone; as recited in claim 9 wherein the image is obtained by magnetic resonance / MRI or MR or computed tomography CT] (see Saha, page 147 at paragraph "These fuzzy connectedness algorithms ...").

Therefore it would have been obvious to one of ordinary skill in the art at the time the invention was made to further modify Borgefors method, as modified by Wang, using Saha's teachings by expanding Borgefors fuzzy connectedness ideas in order to advance the effectiveness of fuzzy connectedness algorithms to the several medical application fields (see Saha, page 147 at paragraph "These fuzzy connectedness algorithms ...").

As to claims 12 and 14-15, the discussions are addressed with respect to claims 6 and 8-9.

17. Claims 17, and 22-25 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borgefors, in view of Lang et al (US 2003/0112921 A1).

Re Claim 17: Borfefors discloses a fuzzy distance transform-based computational method / fuzzy border distance transform for analyzing digital images (see Figs. 2 and 3) defining at least one volumetric region / 2D or higher dimensions such as 3D in the subject / object (see abstract, Section 2 – Fuzzy border distance transforms, Figs. 2 and 3, skeletonization of objects is performed on 2D digital images [also extendible to higher dimensions such as 3D]), the method comprising: (a) obtaining an image of targeted region (see abstract, Section 2 – Fuzzy border distance transforms, Figs. 2 and 3 show obtaining the initial targeted object and then initializing the fuzzy border distance transform and then the resulting skeletonized image produced from the computed fuzzy border distance transform); (b) finding a plurality of points in the image to generate a fuzzy subset / fuzzy border and computing a fuzzy distance transform (FDT) / fuzzy border distance transform of the fuzzy subset / fuzzy border (see abstract, Section 2 – Fuzzy border distance transforms, Figs. 2 and 3 show obtaining the initial targeted object and then initializing the fuzzy border distance transform and then the resulting skeletonized image produced from the computed fuzzy border distance transform); and (c) compiling a plot or revised image / skeletonized image based upon the computed

FDT / fuzzy border distance transform (see abstract, Section 2 – Fuzzy border distance transforms, Figs. 2 and 3 show obtaining the initial targeted object and then initializing the fuzzy border distance transform and then the resulting skeletonized image produced from the computed fuzzy border distance transform).

However Borgefors doesn't explicitly suggest that the object is a bone from or in the subject and that the computational method is for evaluating or diagnosing bone disease in the subject.

Lang discloses providing x-ray images of a bone from or in the subject / bone of patient and that the computational method / skeletonization is for evaluating or diagnosing bone disease in the subject / for monitoring progression of osteoporosis and therapeutic response (see Lang, paragraphs [0210], [0042], [0029]-[0031], a skeletonization of the image data is performed to diagnose bone disease, monitor the progression of bone disease, selecting a therapy based on the evaluation of bone disease and monitoring the progression of bone disease during or after administration of the selected therapy [bone disease being osteoporosis or bone fracture]).

Therefore, it would have been obvious to one of ordinary skill in the art at the time the invention was made to modify Borgefors's method by using Lang's teachings by including to Borgefors's skeletonization technique [using the fuzzy border distance transform] the diagnosis of bone disease of a patient in order to be able to select and administer therapy to the evaluated diagnosis (Lang, paragraphs [0210], [0042], [0029]-[0031]).

Re Claim 22: Lang further discloses selecting a therapy based on the diagnosis or evaluation of bone disease in the subject (see Lang, paragraphs [0210], [0042], [0029]-[0031], a skeletonization of the image data is performed to diagnose bone disease, monitor the progression of bone disease, selecting a therapy based on the evaluation of bone disease and monitoring the progression of bone disease during or after administration of the selected therapy [bone disease being osteoporosis or bone fracture]).

Re Claim 23: Lang further discloses administering said therapy to the subject (see Lang, paragraphs [0210], [0042], [0029]-[0031], a skeletonization of the image data is performed to diagnose bone disease, monitor the progression of bone disease, selecting a therapy based on the evaluation of bone disease and monitoring the progression of bone disease during or after administration of the selected therapy [bone disease being osteoporosis or bone fracture]).

Re Claim 24: Lang further discloses wherein the evaluation further comprises monitoring a progression or regression of bone disease in the subject, during or at one or more times after administering the selected therapy (see Lang, paragraphs [0210], [0042], [0029]-[0031], a skeletonization of the image data is performed to diagnose bone disease, monitor the progression of bone disease, selecting a therapy based on the evaluation of bone disease and monitoring the progression of bone disease during

or after administration of the selected therapy [bone disease being osteoporosis or bone fracture]).

As to claim 25, the claim is the corresponding computer readable medium claim to claim 17 respectively. The discussions are addressed with regard to claim 17. Further, Borgefors fuzzy border distance transform terminates is a finite number of steps (see Borgefors, Figs. 2 and 3, a number of iterations are processed for the skeletonization, but a result is produced). Also, from the skeletonization of the image, the structural thickness of an object from the digital image can be calculated (see Lang, paragraphs [0210], [0042], [0029]-[0031], the bone density and bone structure can be evaluated using skeletonization to help in selecting the therapy).

18. Claims 18-21 and 26-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Borgefors, as modified by Lang, and further in view of Wang. The teachings of Borgefors as modified by Lang have been discussed above.

As to claims 18-21, the discussions are addressed with respect to claims 2-5.

As to claims 26-28, the discussions are addressed with respect to claims 2-4.

The limitation "means for assigning" in line 2 of claim 26 invokes 35 U.S.C 112, sixth paragraph.

Conclusion

19. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bernard Krasnic whose telephone number is (571) 270-1357. The examiner can normally be reached on Mon-Thur 8:00am-4:00pm and every other Friday 8:00am-3:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jingge Wu can be reached on (571) 272-7429. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Jingge Wu/
Supervisory Patent Examiner, Art Unit 2624
Bernard Krasnic
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